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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,388	11/07/2005	Sun Lee	20050-00004	2704

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EXAMINER	
WORLEY, CATHY KINGDON	

ART UNIT	PAPER NUMBER
1638	

MAIL DATE	DELIVERY MODE
10/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,388	LEE ET AL.	
	Examiner	Art Unit	
	Cathy K. Worley	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-6 and 8* is/are rejected.

7)☒ Claim(s) *3 and 7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/3/05; 11/7/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims

1. Claims 1-8 are pending in the instant application and are examined in this Office Action.

Claim Objections

2. Claims 1, 3-5, 7, and 8 are objected to because of the following informalities:

- In claims 1 and 5, the recitation of "the C-terminal or N-terminal of said EGF" is grammatically incorrect. The Applicant is advised to replace this recitation with - - the C-terminus or N-terminus of said EGF - - , or alternatively with - - the C-terminal end or N-terminal end of said EGF - - .
- In claims 3 and 7, the article "a" should be replaced with the article - - the - - in line one in order to clearly refer to the sequence recited in claim 1 and claim 5, respectively. Furthermore, "nucleotide" which appears in the second line should be plural because there are 159 nucleotides in the fragment being claimed.
- In claims 4 and 8, the recitation of "the C-terminal of said EGF" is grammatically incorrect. The Applicant is advised to replace this recitation

with - - the C-terminus of said EGF - - or alternatively, with - - the C-terminal end of said EGF - - .

Appropriate correction is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 2, 4-6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hooker et al (WO 98/21348, published on May 22, 1998) in view of Rosen et al (WO 01/79442, published on Oct. 25, 2001), and further in view of Sijmons et al (US Patent 5,716,802, issued on Feb. 10, 1998).

The claims are drawn to methods of producing fusion proteins comprising epidermal growth factor (EGF) and human serum albumin (HSA) in transgenic plants.

The instant claims are obvious over the prior art because there was some teaching, suggestion, or motivation in the knowledge generally available to one of ordinary skill in the art to combine the reference teachings, and there was a reasonable expectation of success in combining the teachings.

SCOPE AND CONTENT OF THE PRIOR ART – PRIMARY REFERENCE

Hooker et al teach the production of EGF in plants (see entire document). Hooker et al suggest that the EGF can be produced as a fusion with a protein that is efficiently produced in plants systems (see page 6, lines 9-11; and abstract). They teach production in *Nicotiana tabacum* (see page 5, line 25), and also teach that any plant from the plant kingdom may be utilized (see page 7, line 20). Hooker et al teach that a method for producing EGF in a plant comprises the steps of subcloning the coding sequence into a plant expression vector, transferring the vector to *Agrobacterium*, culturing leaf disks or suspension cells with *Agrobacterium*, selecting for transformants, permitting growth of plant cells into whole plants, and extracting the growth factor (see page 8, lines 16-29). They teach that the plant expression vector should comprise a promoter and a terminator (see page 9, lines 5-8).

DIFFERENCES BETWEEN THE CLAIMED INVENTION AND THE TEACHINGS OF HOOKER et al.

Hooker et al do not teach expression of EGF as a fusion with HSA. They do not teach N-terminal or C-terminal fusions with HSA, nor do they teach stability of said fusions.

SCOPE AND CONTENT OF THE PRIOR ART – SECONDARY REFERENCE

Rosen et al teach expression albumin fusion proteins (see entire document). They teach that therapeutic proteins, such as growth hormones, are typically labile

molecules exhibiting short shelf-lives (see page 2, lines 6-7). They teach that therapeutic proteins can be stabilized to extend the shelf-life and/or to retain the therapeutic protein's activity by fusing the therapeutic protein to albumin (see page 2, lines 24-27). Rosen et al teach that the HSA may be fused to either the C-terminus or the N-terminus of the therapeutic protein (see paragraph bridging pages 115-116).

SCOPE AND CONTENT OF THE PRIOR ART – TERTIARY REFERENCE

Sijmons et al teach the production of recombinant HSA in transgenic plants (see column 3, lines 41-46 and Figure 1).

LEVEL OF ORDINARY SKILL IN THE PERTINANT ART

The pertinent art is the field of molecular biology and biochemistry, and one of ordinary skill in this art would have earned a Ph.D. in molecular biology, biochemistry, plant biology, or some other related field. One of ordinary skill in this art would have been well-versed in techniques for heterologous expression of recombinant proteins and would be familiar with the literature encompassing production of fusion proteins and production of therapeutic proteins in plants.

FINDING OF OBVIOUSNESS

At the time the invention was made, it would have been obvious and within the scope of one of ordinary skill in the art to modify the method taught by Hooker et al to produce fusion proteins as taught by Rosen et al. These teachings include each element recited in the instant claims. Because Rosen et al teach that fusing

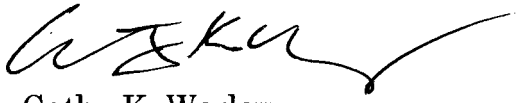
therapeutic proteins to HSA can increase the shelf-life and retain the biological activity of the therapeutic protein, one of ordinary skill in the art would have been motivated to modify the method taught by Hooker et al to produce EGF-HSA or HSA-EGF fusion proteins to arrive at the instant invention. Because of the success in producing EGF in plants taught by Hooker et al, and the success in producing HSA in plants taught by Sijmons et al, and the success in producing stable, biologically active fusion proteins taught by Rosen et al; one would have an expectation of success in producing HSA-EGF or EGF-HSA fusion proteins in plants, and one would have predicted that such fusion proteins would have enhanced stability compared to EGF expressed as a non-fusion protein. For these reasons, the instant claims are obvious over the prior art.

4. Claims 3 and 7 are free of the prior art because the prior art does not teach or fairly suggest the nucleotide sequence of bases 1-159 of SEQ ID NO:1.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cathy K. Worley whose telephone number is (571) 272-8784. The examiner is on a variable schedule but can normally be reached on M-F 10:00 - 4:00 with additional variable hours before 10:00 and after 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cathy K. Worley
Patent Examiner
Art Unit 1638

CKW